

K090352

Special 510(k) Summary

1. Company Identification

Covidien, (formerly Nellcor Puritan Bennett, Inc.)
6135 Gunbarrel Avenue
Boulder, CO 80301

APR - 3 2009

Establishment Registration: 2936999

2. Contact Person

Ted Kuhn
Regulatory Affairs Associate II
Phone: (303) 305-2272
Fax: (303) 305-2212
Email: ted.kuhn@covidien.com

3. 510(k) Preparation Date

February 10, 2009

4. Device Name

Trade Name: TaperGuard™ Endotracheal Tubes and TaperGuard Evac™ Endotracheal Tubes.
Common Name: Endotracheal Tube, Tracheal Tube

5. Device Classification

Class II Tracheal Tube (21 CFR 868.5730), classification code 73 BTR

6. Intended Use

The Hi-Lo, Intermediate Hi-Lo, and TaperGuard™ cuffed endotracheal tubes are indicated for oral/nasal intubation of the trachea for anesthesia and for general airway management. Tubes that are pre-cut to special lengths are intended for oral intubation only.

7. Indications for Use

The TaperGuard Evac™ Endotracheal tube is indicated for airway management by oral/nasal intubation of the trachea and for evacuation or drainage of the subglottic space.

The TaperGuard™ Endotracheal tube is a device inserted into a patient's trachea via the nose or mouth to maintain an open airway.

8. Claims

TaperGuard™ Endotracheal Tubes;

- The TaperGuard™ PVC Tapered Cuff Endotracheal tubes reduce micro aspiration by an average of 90%, in comparison to the Hi-Lo Basic Barrel Shaped PVC Cuff Endotracheal tube.

TaperGuard Evac™ Endotracheal Tubes;

- The TaperGuard PVC Tapered Cuff Evac™ Endotracheal tubes reduce micro aspiration by an average of 90%, in comparison to the Hi-Lo Evac Barrel Shaped PVC Cuff Endotracheal tube.

In specific clinical circumstances, use of the TaperGuard Evac™ Endotracheal Tubes has been associated with a decrease in the rate of nosocomial pneumonia (VAP).

9. Description of Device

TaperGuard™ Endotracheal Tube (5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10mm)

TaperGuard Evac™ Endotracheal Tube - Oral (6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm)

The TaperGuard™ and the TaperGuard Evac™ Tracheal Tubes are sterile, single-use devices supplied with a standard 15mm connector. On the Evac tubes, in addition to the main lumen, the tube has a separate Evac lumen which has a dorsal opening above the cuff. Access to the lumen is accomplished via a clear connecting tube with a capped Luer connector. The tube incorporates a Magill curve, a hooded tip with a Murphy Eye and a Tip-To-Tip™ radiopaque line to assist in radiographic visualization.

10. Substantial Equivalence

The predicate devices to which we claim equivalence are the Hi-Lo Cuffed Tracheal Tubes (K871204), Hi-Lo Evac™ Endotracheal Tubes (K965132), SealGuard Endotracheal Tubes and SealGuard Evac™ Endotracheal Tubes (K082520).

The TaperGuard™ Endotracheal tubes and the TaperGuard Evac™ Endotracheal tubes maintain the same intended use as the predicate devices. It is a device inserted into the trachea through the mouth or nose to facilitate breathing.

The TaperGuard™ Endotracheal tubes, TaperGuard Evac™ Endotracheal tubes and the predicate devices consist of the same fundamental technology.

The TaperGuard™ device differs from the predicate device, SealGuard, in that the tapered cuff is made of PVC for TaperGuard™ and PU for SealGuard. Both devices have a tapered cuff.

The TaperGuard™ device differs from the predicate device, Hi-Lo, in that the TaperGuard™ has a tapered cuff and the Hi-Lo has a barrel shaped cuff. The cuff material for both devices is PVC.

The TaperGuard™ and TaperGuard Evac™ device in all clinical applications will be identical to the use of predicate devices. From a Human Factors perspective none of the changes in any way affect the operation or usability of the tube or cuff.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ted Kuhn
Regulatory Affairs Associate II
Respiratory & Monitoring Solutions
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301

APR - 3 2009

Re: K090352
Trade/Device Name: TaperGuard™ Trachael Tubes and TaperGuard Evac™
Trachael Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Trachael Tube
Regulatory Class: II
Product Code: BTR
Dated: March 20, 2009
Received: March 23, 2009

Dear Mr. Kuhn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

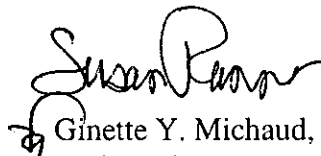
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K090352

Device Name: TaperGuard™ Tracheal Tubes and TaperGuard Evac™ Tracheal Tubes

Indications for Use:

The TaperGuard Evac™ Endotracheal tube is indicated for airway management by oral/nasal intubation of the trachea, and for evacuation or drainage of the subglottic space.

The TaperGuard™ Endotracheal tube is a device inserted into a patient's trachea via the nose or mouth to maintain an open airway.

Prescription Use X
(Part 21 CFR 801 Subpart D)
C)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices